



08.29.05

IPW

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Application No. : 10/735,601
Confirmation No. : 2496
Applicant: Smith et al.
Filed: December 12, 2003
Group Art Unit : 1632
Examiner: Not assigned
For : Multi-antigenic Alphavirus Replicon Particles and Methods
Docket No. : 95-02
Customer No. : 23713

SUPPLEMENTAL INFORMATION DISCLOSURE STATEMENT

MAIL STOP AMENDMENT
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Further to the Information Disclosure Statement filed October 12, 2004, the Examiner is respectfully requested to consider the additional references, copies enclosed, which may qualify as prior art. For the Examiner's Convenience, the references are listed on the attached Patent and Trademark Office Form PTO-1449. Pursuant to the Waiver of the Copy Requirement in 37 C.F.R. 1.98 for Cited Pending U.S. Patent Applications signed on September 21, 2004 and published on www.uspto.gov on September 24, 2004, copies of pending U.S. applications that are available in the Image File Wrapper system are not submitted, but will be provided on request.

This information is cited in a spirit of forthrightness and cooperation to enable the applicants to obtain that measure of protection for the invention to which there is entitlement. However, no representation is made that the listed art actually qualifies as prior art under the patent statute and the mere use of PTO-1449 is not an admission that all listed references are prior art. No representation is made that applicants know of the best art.

It is believed this submission does not require the payment of a fee as it is being submitted prior to the issuance of an Office Action on the merits of the application. If this is incorrect, please deduct the appropriate fee from deposit account no. 07-1969.

It is believed that this submission does not require the payment of any fees. If this is incorrect, however, please deduct the appropriate fee from deposit account 07-1969.

Respectfully submitted,



Donna M. Ferber
Reg. No. 33,878

GREENLEE, WINNER AND SULLIVAN, P.C.
4875 Pearl East Circle, Suite 200, Boulder, CO 80301
Telephone: (303) 499-8080; Facsimile: (303) 499-8089
Attorney Docket No. 95-02
Item: August 26, 2005

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

| | |
|------------------------|--------------------|
| Application Number | 10/735,601 |
| Filing Date | 12/12/2003 |
| First Named Inventor | Smith et al. |
| Art Unit | 1635 |
| Examiner Name | Brian A. Whitemann |
| Attorney Docket Number | 95-02 |

GWS 8/19/2005

AUG 26 2005

U.S. PATENT DOCUMENTS

| Examiner Initial ¹ | Cite No. ¹ | Document Number (US-) | Publication Date (MM-DD-YYYY) | Name | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise) |
|-------------------------------|-----------------------|-----------------------|-------------------------------|----------------------|---|
| | 1 | 6,844,188 | 01/18/2005 | MacDonald et al. | |
| | 2 | 6,783,939 | 08/31/2004 | Olmsted et al. | |
| | 3 | 6,583,121 | 06/24/2003 | Johnston et al. | |
| | 4 | 6,451,592 | 09/17/2002 | Dubensky, Jr. et al. | |
| | 5 | 6,426,196 | 07/30/2002 | Dubensky, Jr. et al. | |
| | 6 | 6,391,632 | 05/21/2002 | Dubensky, Jr. et al. | |
| | 7 | 6,376,236 | 04/23/2002 | Dubensky, Jr. et al. | |
| | 8 | 6,342,372 | 01/29/2002 | Dubensky, Jr. et al. | |
| | 9 | 6,329,201 | 12/11/2002 | Polo et al. | |
| | 10 | 6,261,570 | 07/17/2002 | Parker et al. | |
| | 11 | 6,224,879 | 05/01/2002 | Sjoberg et al. | |
| | 12 | 6,156,558 | 12/05/2000 | Johnston et al. | |
| | 13 | 6,146,874 | 11/14/2000 | Zolotukhin et al. | |
| | 14 | 6,015,694 | 01/18/2000 | Dubensky, Jr. et al. | |
| | 15 | 6,015,686 | 01/18/2000 | Dubensky, Jr. et al. | |
| | 16 | 6,008,035 | 12/28/1999 | Johnston et al. | |
| | 17 | 5,843,723 | 12/01/1998 | Dubensky, Jr. et al. | |
| | 18 | 5,814,482 | 09/29/1998 | Dubensky, Jr. et al. | |
| | 19 | 5,789,245 | 08/04/1998 | Dubensky, Jr. et al. | |
| | 20 | 5,766,602 | 06/16/1998 | Xiong et al. | |
| | 21 | 5,739,026 | 04/14/1998 | Garoff et al. | |
| | 22 | 5,217,879 | 06/08/1993 | Huang et al. | |
| | 23 | 5,091,309 | 02/25/1992 | Schlesinger et al. | |
| | 24 | 4,708,871 | 11/24/1987 | Geysen | |
| | 25 | 2005/0123555 | 06/09/2005 | Olmsted et al. | |
| | 26 | 2005/0054107 | 03/10/2005 | Chulay et al. | |
| | 27 | 2004/0235133 | 11/25/2004 | Frolov et al. | |
| | 28 | 2004/0029278 | 02/12/2004 | Dubensky et al. | |
| | 29 | 2003/0232035 | 12/18/2003 | Dubensky et al. | |
| | 30 | 2003/0148262 | 08/07/2003 | Polo et al. | |
| | 31 | 2003/0119182 | 06/26/2003 | Smith et al. | |
| | 32 | 2002/0141975 | 10/03/2002 | Olmsted et al. | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

| | | | |
|---|--|------------------------|--------------------|
| Substitute for form 1449/PTO, based on PTO/SB/08A and 08B | | Application Number | 10/735,601 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Filing Date | 12/12/2003 |
| | | First Named Inventor | Smith et al. |
| | | Art Unit | 1635 |
| | | Examiner Name | Brian A. Whitemann |
| | | Attorney Docket Number | 95-02 |
| | | | |

GWS 8/19/2005

FOREIGN PATENT DOCUMENTS

| Examiner Initial* | Cite No. ¹ | Foreign Patent Document Number (include WIPO country code) | Publication Date (MM-DD-YYYY) | Name | Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear (or entire document unless noted otherwise) | T ² |
|-------------------|-----------------------|--|----------------------------------|----------------------|---|----------------|
| | 33 | WO 04/085660 | 10/07/2004 | Smith et al. | | |
| | 34 | WO 03/023026 A | 03/20/2003 | Smith et al. | | |
| | 35 | WO 02/20721 | 03/14/2002 | Johnston et al. | | |
| | 36 | WO 00/61772 | 10/19/2000 | Polo et al. | | |
| | 37 | WO 00/39318 | 07/06/2000 | Polo et al. | | |
| | 38 | WO 96/37616 | 11/28/1996 | Johnston et al. | | |
| | 39 | WO 96/37220 | 11/28/1996 | Johnston et al. | | |
| | 40 | WO 96/17072 | 06/06/1996 | Dubensky, Jr. et al. | | |
| | 41 | WO 95/31565 | 11/23/1995 | Sjoberg et al. | | |
| | 42 | WO 95/27044 | 10/12/1995 | Liljestrom et al. | | |
| | 43 | WO 95/07994 | 03/23/1995 | Dubensky, Jr. et al. | | |
| | 44 | WO 92/10578 | 06/25/1992 | Garoff et al. | | |

NON-PATENT LITERATURE DOCUMENTS

| Examiner Initial* | Cite No. ¹ | REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-------------------|-----------------------|--|----------------|
| | 45 | Barouch et al. (2000) "Augmentation of Immune Responses to HIV-1 and Simian Immunodeficiency Virus DNA Vaccines by IL-2/Ig Plasmid Administration in Rhesus Monkeys," <i>Proc. Natl. Acad. Sci. USA</i> 97(8):4192-4197 | |
| | 46 | Berglund et al. (1993) "Semliki Forest Virus Expression System: Production of Conditionally Infectious Recombinant Particles," <i>Bio/Technology</i> 11:916-920 | |
| | 47 | Betts et al. (1997) "Cross-Clade Human Immunodeficiency Virus (HIV)-Specific Cytotoxic T-Lymphocyte Responses in HIV-Infected Zambians," <i>J. Virol.</i> 71(11):8908-8911 | |
| | 48 | Bredenbeek et al. (1993) "Sindbis Virus Expression Vectors: Packaging of RNA Replicons by Using Defective Helper RNAs," <i>J. Virol.</i> 67:6439-6446 | |
| | 49 | Caley et al. (1997) "Humoral, Mucosal, and Cellular Immunity in Response to a Human Immunodeficiency Virus Type 1 Immunogen Expressed by a Venezuelan Equine Encephalitis Virus Vaccine Vector," <i>J. Virol.</i> 71(4):3031-3038 | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

| | |
|------------------------|--------------------|
| Application Number | 10/735,601 |
| Filing Date | 12/12/2003 |
| First Named Inventor | Smith et al. |
| Art Unit | 1635 |
| Examiner Name | Brian A. Whitemann |
| Attorney Docket Number | 95-02 |

GWS 8/19/2005

| Examiner Initial* | Cite No. ¹ | REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-------------------|-----------------------|--|----------------|
| | | | |
| | 50 | Caley et al. (1999) "Venezuelan Equine Encephalitis Virus Vectors Expressing HIV-1 Proteins: Vector Design Strategies for Improved Vaccine Efficacy," <i>Vaccine</i> 17:3124-3135 | |
| | 51 | Chappell et al. (Feb. 2000) "A 9-nt Segment of a Cellular mRNA can Function as an Internal Ribosome Site (IRES) and When Present in Linked Vaccine Efficacy," <i>Proc. Natl. Acad. Sci. USA</i> 97(4):1536-1541 | |
| | 52 | Corsini et al. (1996) "Efficiency of Transduction by Recombinant Sindbis Replicon Virus Varies Among Cell Lines, Including Mosquito Cells and Rat Sensory Neurons," <i>BioTechniques</i> 21(3):492-497 | |
| | 53 | Cutler et al. (1986) "Mutants of the Membrane-binding Region of Semliki Forest Virus E2 Protein. I. Cell Surface Transport and Fusogenic Activity," <i>J. Cell Biol.</i> 102:889-901 | |
| | 54 | Davis et al. (1993) "A Genetically Engineered Live Virus Vaccine for Venezuelan Equine Encephalitis," <i>J. Cell Biochem. Supp O</i> No.17 part D, Abstract N404 | |
| | 55 | Davis et al. (1996) "A Viral Vaccine Vector that Expresses Foreign Genes in Lymph Nodes and Protects Against Mucosal Challenge," <i>J. Virol.</i> 70:3781-3787 | |
| | 56 | Davis et al. (1995) "Attenuated Mutants of Venezuelan Equine Encephalitis Virus Containing Lethal Mutations in the PE2 Cleavage Signal Combined with a Second-Site Suppressor Mutation in E1," <i>Virol.</i> 212:102-110 | |
| | 57 | Davis et al. (1991) "Attenuating Mutations in the E2 Glycoprotein Gene of Venezuelan Equine Encephalitis Virus: Construction of Single and Multiple Mutants in a Full-Length cDNA Clone," <i>Virol.</i> 183:20-31 | |
| | 58 | Davis et al. (1996) "Immunization Against Influenza with Attenuated Venezuelan Equine Encephalitis Virus Vectors," In: <i>Options for the Control of Influenza III</i> , L.E.Brown and A.W.Hampson, eds. Elsevier, Amsterdam pp.803-809 | |
| | 59 | Davis et al. (1990) "In Vitro Synthesis of Infectious Venezuelan Equine Encephalitis Virus RNA from a cDNA Clone: Analysis of a Viable Deletion Mutant and Mutations Affecting Virulence," <i>Vaccines</i> 90:109-113 | |
| | 60 | Davis et al. (1989) "In Vitro Synthesis of Infectious Venezuelan Equine Encephalitis Virus RNA from a cDNA Clone: Analysis of a Viable Deletion Mutant," <i>Virol.</i> 171:189-204 | |
| | 61 | Davis et al. (2001) "Vaccination of Macaques Against Pathogenic Simian Immunodeficiency Virus with Venezuelan Equine Encephalitis Virus Replicon Particles," <i>J. Virol.</i> 74(1):371-378 | |
| | 62 | Davis et al. (1994) "A Molecular Genetic Approach to the Study of Venezuelan Equine Encephalitis Virus Pathogenesis," <i>Arch. Virol.</i> 9:99-109 | |
| | 63 | Dubensky et al. (1996) "Sindbis Virus DNA-Based Expression Vectors: Utility for in Vitro and in Vivo Gene Transfer," <i>J. Virol.</i> 70:508-519 | |
| | 64 | Dubuisson et al. (1993) "Sindbis Virus Attachment: Isolation and Characterization of Mutants With Impaired Binding to Vertebrate Cells," <i>J. Virol.</i> 67:3363-3374 | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

| | |
|------------------------|---------------------------|
| Application Number | 10/735,601 |
| Filing Date | 12/12/2003 |
| First Named Inventor | Smith et al. |
| Art Unit | 1635 |
| Examiner Name | Brian A. Whitemann |
| Attorney Docket Number | 95-02 |

GWS 8/19/2005

| Examiner Initial* | Cite No. ¹ | REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-------------------|-----------------------|--|----------------|
| | | | |
| | 65 | Favre et al. (1993) "Semliki Forest Virus Capsid Protein Expressed by a Baculovirus Recombinant," <i>Arch. Virol.</i> 132:307-319 | |
| | 66 | Feyzi et al (1997) "Structural Requirement of Heparan Sulfate for Interaction with Herpes Simplex Virus Type 1 Virions and Isolated Glycoprotein C," <i>J. Biol. Chem.</i> 272(40):24850-24857 | |
| | 67 | Garoff et al. (1983) "Expression of Semliki Forest Virus Proteins from Cloned Complementary DNA. II. The Membrane-Spanning Glycoprotein E2 is Transported to the Cell Surface Without its Normal Cytoplasmic Domain," <i>J. Cell Biol.</i> 97:652-658 | |
| | 68 | Geigenmuller-Gnirke et al. (1991) "Complementation Between Sindbis Viral RNAs Produce Infectious Particles with a Bipartite Genome," <i>Proc. Natl. Acad. Sci. USA.</i> 88:3253-3257 | |
| | 69 | Gingras et al. (1996) "Activation of the Translational Suppressor 4E-BP1 Following Infection with Encephalomyocarditis Virus and Poliovirus," <i>Proc. Natl. Acad. Sci. USA</i> 93:5578-5583 | |
| | 70 | Gradi et al. (1998) "Proteolysis of Human Eukaryotic Translation Initiation Factor eIF4GII, but Not eIF4GI, Coincides with the Shutoff of Host Protein Synthesis after Poliovirus Infection," <i>Proc. Natl. Acad. Sci. USA</i> 95:11089-11094 | |
| | 71 | Grieder et al. (1995) "Specific Restrictions in the Progression of Venezuelan Equine Encephalitis Virus-Induced Disease Resulting from Single Amino Acid Changes in Glycoproteins," <i>Virol.</i> 206:994-1006 | |
| | 72 | Heidner et al. (1994) "Lethality of PE2 Incorporation into Sindbis Virus can be Suppressed by Second-Site Mutations in E3 and E2," <i>J. Virol.</i> 68:2683-2692 | |
| | 73 | Heise et al. (Jan. 2003) "An Attenuation Mutation in nsP1 of the Sindbis-Group Virus S.A.AR86 Accelerates Nonstructural Protein Processing and Up Regulates Viral 26S RNA Synthesis," <i>J. Virol.</i> 77(2):1149-1156 | |
| | 74 | Herweijer et al. (1997) "Self-Amplifying Vectors for Gene Delivery," <i>Adv. Drug Rev.</i> 27:5-16 | |
| | 75 | Hevey et al. (Nov. 2001) "Marburg Virus Vaccines: Comparing Classical and New Approaches," <i>Vaccine</i> 20:586-593 | |
| | 76 | Hirsch et al. (1996) "Patterns of Viral Replication Correlate with Outcome in Simian Immunodeficiency Virus (SIV)-Infected Macaques: Effect of Prior Immunization with a Trivalent SIV Vaccine in Modified Vaccinia Virus Ankara," <i>J. Virol.</i> 70(6):3741-3752 | |
| | 77 | Hodgson et al. (1993) "Expression of Venezuelan Equine Encephalitis Viral Proteins by Recombinant Baculoviruses," <i>Am. J. Trop. Med. Hygiene</i> 49:195-196 | |
| | 78 | Holcik et al. (2000) "Functional Characterization of the X-Linked Inhibitor of Apoptosis (XIAP) Internal Ribosome Entry Site Element: Role of La Autoantigen in XIAP Translation," <i>Mol. Cell. Biol.</i> 20(13):4648-4657 | |
| | 79 | Holcik et al. (1999) "A New Internal-Ribosome-Entry-Site Motif Potentiates XIAP-Mediated Cytoprotection," <i>Nature Cell Biol.</i> 1:190-192 | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

| | |
|------------------------|--------------------|
| Application Number | 10/735,601 |
| Filing Date | 12/12/2003 |
| First Named Inventor | Smith et al. |
| Art Unit | 1635 |
| Examiner Name | Brian A. Whitemann |
| Attorney Docket Number | 95-02 |

GWS 8/19/2005

| Examiner Initial* | Cite No. ¹ | REFERENCE | T ² |
|-------------------|-----------------------|---|----------------|
| | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
| | 80 | Holcik et al. (Jan. 2003) "The Internal Ribosome Entry Site-Mediated Translation of Antiapoptotic Protein XIAP is Modulated by the Heterogeneous Nuclear Ribonucleoproteins C1 and C2," <i>Mol. Cell. Biol.</i> 23(1):280-288 | |
| | 81 | International Search Report of International Application Serial No. PCT/US02/28610 filed September 6, 2002 | |
| | 82 | International Search Report Corresponding to PCT/US 2004/008458 Filed October 25, 2004 | |
| | 83 | Jalanko (1985) "Expression of Semliki Forest Virus Capsid Protein from SV40 Recombinant Virus," <i>FEBS Lett.</i> 186:59-64 | |
| | 84 | Jang et al. (1990) "Cap-Independent Translation of Encephalomyocarditis Virus RNA: Structural Elements of the Internal Ribosomal Entry Site and Involvement of a Cellular 57kD RNA-Binding Protein," <i>Genes and Development</i> 4:1560-1572 | |
| | 85 | Joachims et al. (1999) "Cleavage of Poly(A)-Binding Protein by Enterovirus Proteases Concurrent with Inhibition of Translation <i>In Vitro</i> ," <i>J. Virol.</i> 73(1):718-727 | |
| | 86 | Johnston et al. (1996) "Alphaviruses," In: <i>Fields Virology</i> , 3 rd ed., Lippincott-Raven Publishers, Philadelphia, Chapt 28:843-898 | |
| | 87 | Johnston et al. (1988) "Selection for Accelerated Penetration in Cell Culture Coselects for Attenuated Mutants of Venezuelan Equine Encephalitis Virus," <i>Virol.</i> 162:437-443 | |
| | 88 | Kinney et al. (1993) "Attenuation of Venezuelan Equine Encephalitis Virus Strain TC-83 Is Encoded by the 5'-Noncoding Region and the E2 Envelope Glycoprotein," <i>J. Virol.</i> 67:1269-1277 | |
| | 89 | Knight (1999) "Secretion from Bovine Chromaffin Cells Acutely Expressing Exogenous Proteins using a Recombinant Semliki Forest Virus Containing an EGFP Reporter," <i>Mol. Cell. Neuro.</i> 14(6):486-505 | |
| | 90 | Kohl et al. (1999) "Transient Gene Expression in Mammalian and Mosquito Cells Using a Recombinant Semliki Forest Virus Expressing T7 RNA Polymerase," <i>Appl. Microbiol. Biotechnol.</i> 53(1):51-56 | |
| | 91 | Kondor-Koch et al. (1983) "Expression of Semliki Forest Virus Proteins from Cloned Complementary DNA. I. The Fusion Activity of the Spike Glycoprotein," <i>J. Cell. Biol.</i> 97(3):644-651 | |
| | 92 | Lee et al. (1997) "Efficient Long-Term Coexpression of a Hammerhead Ribozyme Targeted to the U5 Region of HIV-1 LTR by Linkage to the Multidrug-Resistance Gene," <i>Antisense & Nucleic Acid Drug Development</i> 7:511-522 | |
| | 93 | Lemm et al. (1994) "Polypeptide Requirements for Assembly of Functional Sindbis Virus Replication Complexes: A Model for the Temporal Regulation of Minus-and Plus-Strand RNA Synthesis," <i>EMBO J.</i> 13:2925-2934 | |
| | 94 | Leone et al. (1985) "In Vitro Synthesis of the Gene Coding for the Glycoprotein E1 of Sindbis Virus," <i>Microbiologica</i> 8(2):123-130 | |
| | 95 | Li et al. (1996) "Production of Infectious Recombinant Moloney Murine Leukemia | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

| | | |
|---|--|---|
| Substitute for form 1449/PTO, based on PTO/SB/08A and 08B INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Application Number 10/735,601 |
| | | Filing Date 12/12/2003 |
| | | First Named Inventor Smith et al. |
| | | Art Unit 1635 |
| | | Examiner Name Brian A. Whitemann |
| | | Attorney Docket Number 95-02 |

GWS 8/19/2005

| Examiner Initial* | Cite No. ¹ | REFERENCE | T ² |
|--------------------|-----------------------|---|----------------|
| | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
| | | Virus Particles in BHK Cells Using Semliki Forest Virus-Derived RNA Expression Vectors," <i>Proc. Natl. Acad. Sci. USA</i> 93:11658-11663 | |
| | 96 | Liljestrom et al. (1991) "A New Generation of Animal Cell Expression Vectors Based on the Semliki Forest Virus Replicon." <i>BioTechnology</i> 9:1356-1361 | |
| | 97 | Liljestrom (1994) "Alphavirus Expression Systems," <i>Curr. Opin. Biotechnol.</i> 5:495-500 | |
| | 98 | Lobigs et al. (1990) "Fusion Function of the Semliki Forest Virus Spike is Activated by Proteolytic Cleavage of the Envelope Glycoprotein Precursor p62," <i>J. Virol.</i> 64:1233-1240 | |
| | 99 | Lundstrom et al. (1985) "Secretion of Semliki Forest Virus Membrane Glycoprotein E1 from <i>Bacillus subtilis</i> ," <i>Virus Res.</i> 2:69-83 | |
| | 100 | Martinez-Salas et al. (May 2001) "Functional Interactions in Internal Translation Initiation Directed by Viral and Cellular IRES Elements," <i>J. Gen. Virol.</i> 82:973-984 | |
| | 101 | McKnight et al. (1996) "Deduced Consensus Sequence of Sindbis Virus Strain AR339: Mutations Contained in Laboratory Strains which Affect Cell Culture and <i>In Vivo</i> Phenotypes," <i>J. Virol.</i> 70(3):1981-1989 | |
| | 102 | Melancon et al. (1987) "Processing of the Semliki Forest Virus Structural Polyprotein: Role of Capsid Protease," <i>J. Virol.</i> 61:1301-1309 | |
| | 103 | Melancon et al. (1986) "Reinitiation of Translocation in the Semliki Forest Virus Structural Polyprotein: Identification of the Signal for the E1 Glycoprotein," <i>EMBO J.</i> 5:1551-1560 | |
| | 104 | Morgenstern et al. (1990) "Advanced Mammalian Gene Transfer: High Titre Retroviral Vectors with Multiple Drug Selection Markers and a Complementary Helper-Free Packaging Cell Line," <i>Nuc. Acid. Res.</i> 18:3587-3596 | |
| | 105 | Oker-Blom et al. (1989) "Expression of Sindbis Virus 26S cDNA in <i>Spodoptera frugiperda</i> (Sf9) Cells, Using a Baculovirus Expression Vector," <i>J. Virol.</i> 63:1256-1264 | |
| | 106 | Orkin et al. (1995) "Report and Recommendations of the Panel to Assess the NIH Investment in Research on Gene Therapy" | |
| | 107 | Paredes et al. (1993) "Three-Dimensional Structure of a Membrane-Containing Virus," <i>Proc. Natl. Acad. Sci. USA</i> 90:9095-9099 | |
| | 108 | Polo et al. (1990) "Attenuating Mutations in Glycoproteins E1 and E2 of Sindbis Virus Produces a Highly Attenuated Strain When Combined in Vitro," <i>J. Virol.</i> 64:4438-4444 | |
| | 109 | Presley et al. (1991) "Proteolytic Processing of the Sindbis Virus Membrane Protein Precursor PE2 is Nonessential for Growth in Vertebrate Cells but is required for Efficient Growth in Invertebrate Cells," <i>J. Virol.</i> 65:1905-1909 | |
| | 110 | Pugachev et al. (2000) "Development of a Rubella Virus Vaccine Expression Vector: Use of a Picornavirus Internal Ribosome Entry Site Increases Stability of Expression," <i>J. Virol.</i> 74:10811-10815 | |
| | 111 | Pushko et al. (Dec. 2001) "Individual and Bivalent Vaccines Based on Alphavirus Replicons Protect Guinea Pigs Against Infection with Lassa and Ebola Viruses," <i>J.</i> | |
| Examiner Signature | | Date Considered | |

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.

Substitute for form 1449/PTO, based on PTO/SB/08A and 08B

**INFORMATION DISCLOSURE
STATEMENT BY APPLICANT**

| | |
|------------------------|--------------------|
| Application Number | 10/735,601 |
| Filing Date | 12/12/2003 |
| First Named Inventor | Smith et al. |
| Art Unit | 1635 |
| Examiner Name | Brian A. Whitemann |
| Attorney Docket Number | 95-02 |

GWS 8/19/2005

| Examiner Initial* | Cite No. ¹ | REFERENCE Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | T ² |
|-------------------|-----------------------|--|----------------|
| | | | |
| | | <i>Virol.</i> 75(23):11677-11685- | |
| | 112 | Pushko et al. (1997) "Replicon-Helper Systems from Attenuated Venezuelan Equine Encephalitis Virus: Expression of Heterologous Genes in Vitro and Immunization Against Heterologous Pathogens in Vivo," <i>Virol.</i> 239:389-401 | |
| | 113 | Rayner et al. (Sept. 2002) "Alphavirus Vectors and Vaccination," <i>Rev. Med. Virol.</i> 12(5):279-296 | |
| | 114 | Rice et al. (1985) "Expression of Sindbis Virus Structural Proteins via Recombinant Vaccinia Virus: Synthesis, Processing, and Incorporation into Mature Sindbis Virions," <i>J. Virol.</i> 56:227-239 | |
| | 115 | Riedel (1985) "Different Membrane Anchors Allow the Semliki Forest Virus Spike Subunit E2 to Reach the Cell Surface," <i>J. Virol.</i> 54:224-228 | |
| | 116 | Roberts et al. (1997) "Complementation of Defective Picornavirus Internal Ribosome Entry Site (IRES) Elements by the Coexpression of Fragments of the IRES," <i>Virol.</i> 227:53-62 | |
| | 117 | Russell et al. (1989) "Sindbis Virus Mutations Which Coordinate Affect Glycoprotein Processing, Penetration, and Virulence in Mice," <i>J. Virol.</i> 63:1619-1629 | |
| | 118 | Salminen et al. (1992) "Membrane Fusion Process of Semliki Forest Virus II: Cleavage-Dependant Reorganization of the Spike Protein Complex Controls Virus Entry," <i>J. Cell. Biol.</i> 116:349-357 | |
| | 119 | Schlesinger et al. (1996) "Togaviridae: The Viruses and Their Replication," In: <i>Fields Virology</i> , 3 rd Edition, Lipincott-Raven Publishers, Philadelphia, pp.825-841 | |
| | 120 | Schlesinger et al. (1994) "Recombination Between Sindbis Virus RNAs," <i>J. Virol.</i> 65:4017-4025 | |
| | 121 | Schoepp et al. (1993) "Directed Mutagenesis of a Sindbis Virus Pathogenesis Site," <i>Virol.</i> 193:149-159 | |
| | 122 | Shi et al. (May 2002) "Construction and Characterization of Subgenomic Replicons of New York Strain of West Nile Virus," <i>Virol.</i> 296(2):219-233 | |
| | 123 | Simpson et al. (1996) "Complete Nucleotide Sequence and Full Length cDNA Clone of S.A.Ar86, a South African Alphavirus Related to Sindbis," <i>Virol.</i> 222:464-469 | |
| | 124 | Sjoberg et al. (1994) "A Significantly Improved Semliki Forest Virus Expression System Based on Translation Enhancer Segments from the Viral Capsid Gene," <i>BioTechnol.</i> 12:1127-1131 | |
| | 125 | Strauss et al. (1990) "Alphavirus Proteinases," <i>Sem. Virol.</i> 1:347-356 | |
| | 126 | Strauss et al. (1994) "The Alphaviruses: Gene Expression, Replication, and Evolution," <i>Microbiological Rev.</i> 58:491-562 | |
| | 127 | Suomalainen et al. (1992) "Spike Protein-Nucleocapsid Interactions Drive the Budding of Alphaviruses," <i>J. Virol.</i> 66(8):4737-4747 | |
| | 128 | Sykes et al. (1999) "Genetic Live Vaccines Mimic the Antigenicity but Not | |

| | | | |
|--------------------|--|-----------------|--|
| Examiner Signature | | Date Considered | |
|--------------------|--|-----------------|--|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "X" if English language Translation is attached.

| | | | |
|---|--|------------------------|--------------------|
| Substitute for form 1449/PTO, based on PTO/SB/08A and 08B | | Application Number | 10/735,601 |
| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | Filing Date | 12/12/2003 |
| | | First Named Inventor | Smith et al. |
| | | Art Unit | 1635 |
| | | Examiner Name | Brian A. Whitemann |
| | | Attorney Docket Number | 95-02 |

GWS 8/19/2005

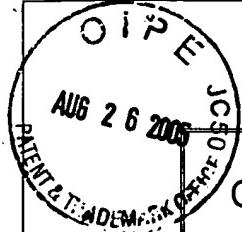
| Examiner Initial* | Cite No. ¹ | REFERENCE | T ² |
|-------------------|---|---|----------------|
| | | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. | |
| | | Pathogenicity of Live Viruses," <i>DNA Cell Biol.</i> 18(7):521-531 | |
| 129 | Thompson et al. (Oct. 2003) "Enterovirus 71 Contains a Type I IRES Element that Functions When Eukaryotic Initiation Factor eIF4G is Cleaved," <i>Virol.</i> 315:259-266 | | |
| 130 | Ubol et al. (1994) "Neurovirulent Strains of Alphavirus Induce Apoptosis in bcl-2-Expressing Cells: Role of A Single Amino Acid Change in the E2 Glycoprotein," <i>Proc. Natl. Acad. Sci. USA</i> 91:5202-5206 | | |
| 131 | Van der Velden et al. (1995) "Defective Point Mutants of the Encephalomyocarditis Virus Internal Ribosome Entry Site can be Complemented <i>in Trans</i> ," <i>Virol.</i> 214:82-90 | | |
| 132 | Verma et al. (1997) "Gene Therapy – Promise and Prospects," <i>Nature</i> 389:239-242 | | |
| 133 | Wang et al. (2000) "Core Protein-Coding Sequence, But Not Core Protein, Modulates the Efficiency of Cap-Independent Translation Directed by the Internal Ribosome Entry Site of Hepatitis C Virus," <i>J. Virol.</i> 74(23):11347-11358 | | |
| 134 | Weiss et al. (1991) "Recombination Between Sindbis Virus RNAs," <i>J. Virol.</i> 65:4017-4025 | | |
| 135 | Wen et al. (1986) "Expression of Genes Encoding Vesicular Stomatitis and Sindbis Virus Glycoproteins in Yeast Leads to Formation of Disulfide-Linked Oligomers," <i>Virol.</i> 153:150-154 | | |
| 136 | Wen et al. (2001) "Tricistronic Viral Vectors Co-Expressing Interleukin-12 (IL-12) and CD80 (B7-1) for the Immunotherapy of Cancer: Preclinical Studies in Myeloma," <i>Cancer Gene Therapy</i> 8(5):361-370 | | |
| 137 | Williamson et al. (Feb. 2003) "Characterization and Selection of HIV-1 Subtype C Isolates for Use in Vaccine Development," <i>AIDS Research and Human Retroviruses</i> 19(2):133-144 | | |
| 138 | Wilson et al. (2000) "Naturally Occurring Dicistronic Cricket Paralysis Virus RNA is Regulated by Two Internal Ribosome Entry Sites," <i>Mol. Cell. Biol.</i> 20(14):4990-4999 | | |
| 139 | Xiong et al. (1989) "Sindbis Virus: An Efficient, Broad Host Range Vector for Gene Expression in Animal Cells," <i>Science</i> 243:1188-1191 | | |
| 140 | Yang et al. (1997) "Location of the Internal Ribosome Entry Site in the 5'Non-Coding Region of the Immunoglobulin Heavy-Chain Binding Protein (BiP) mRNA: Evidence for Specific RNA-Protein Interactions," <i>Nuc. Acids. Res.</i> 25(14):2800-2807 | | |
| 141 | Zhao et al. (1992) "Role of Cell Surface Spikes in Alphavirus Budding," <i>J. Virol.</i> 66:7089-7095 | | |

| | |
|--------------------|-----------------|
| Examiner Signature | Date Considered |
|--------------------|-----------------|

*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹Applicant's unique citation designation number (optional).

²Applicant is to place a check mark here or "x" if English language Translation is attached.



CERTIFICATE OF MAILING BY "EXPRESS MAIL" (37 CFR 1.10)

Attorney Docket No.: 95-02

Application No. : 10/735,601
Applicant: : Smith et al.
Filed: : December 12, 2003
For: : Multi-antigenic Alphavirus Replicon Particles and Methods

I hereby certify that the following correspondence, along with any other document referred to as being attached or enclosed,:

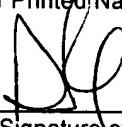
1. Supplemental Information Disclosure Statement – 2 pages
2. Form 1449 – 8 pages
3. 109 references
4. Certificate of Mailing – 1 page
5. Return Postcard

Is being deposited with the United States Postal Service "Express Mail Post Office to Addressee" service under 37 CFR 1.10 in an envelope addressed to:

Commissioner for Patents,
PO Box 1450
Alexandria, VA 22313-1450

On August 26, 2005

Donna M. Ferber
(Typed or Printed Name of Person Mailing Correspondence)


(Signature of Person Mailing Correspondence)

EV 642 816 825 US

("Express Mail" Mailing Label Number)